

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year)

04 DEC 2019

Applicant's or agent's file reference
MONS:464WO

FOR FURTHER ACTION

See paragraph 2 below

International application No. PCT/US 19/44845	International filing date (day/month/year) 02 August 2019 (02.08.2019)	Priority date (day/month/year) 03 August 2018 (03.08.2018)
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International Patent Classification (IPC) or both national classification and IPC

IPC - C12N 15/82, C12N 5/04 (2019.01)

CPC - C12N 15/8274, C12N 15/8216, C12N 15/8261, C12N 15/8279, C12N 5/04

Applicant **MONSANTO TECHNOLOGY LLC**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Date of completion of this opinion 09 October 2019	Authorized officer Lee Young PCT Help Desk Telephone No. 571-272-4300
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b)).

3. ☒ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

- a. ☒ forming part of the international application as filed:
- ☒ in the form of an Annex C/ST.25 text file.
- ☐ on paper or in the form of an image file.
- b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
- c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
- ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).
- ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees.
- ☐ paid additional fees under protest and, where applicable, the protest fee.
- ☐ paid additional fees under protest but the applicable protest fee was not paid.
- ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Groups I+: Claims 1-17, drawn to a recombinant DNA molecule comprising a DNA sequence having gene-regulatory activity, and a method of use thereof. The composition will be searched to the extent that the recombinant DNA molecule encompasses a DNA sequence of SEQ ID NO: 1. It is believed that claims 1-17 encompass this first named invention, and thus these claims will be searched without fee to the extent that they encompass SEQ ID NO: 1. Additional recombinant DNA molecule(s) will be searched upon the payment of additional fees. Applicants must specify the claims that encompass any additionally elected recombinant DNA molecule(s). Applicants must further indicate, if applicable, the claims which encompass the first named invention, if different than what was indicated above for this group. Failure to clearly identify how any paid additional invention fees are to be applied to the "+" group(s) will result in only the first claimed invention to be searched. An exemplary election would be a recombinant DNA molecule encompassing a DNA sequence of SEQ ID NO: 26 (Claims 1-17).

The inventions listed as Groups I+ do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

No technical features are shared between the polynucleotide sequences of Groups I+ and, accordingly, these groups lack unity a priori.

Additionally, even if Groups I+ were considered to share the technical features of including: a recombinant DNA molecule, these shared technical features are previously disclosed by US 2016/0177326 A1 to Monsanto Technology, LLC. (hereinafter "Monsanto").

Monsanto teaches (instant claim 1) a recombinant DNA molecule (Abstract - "The invention provides novel recombinant DNA molecules and constructs useful for modulating gene expression in plants") comprising a DNA sequence comprising synthetic promoter, leader, enhancer, intron or 3' UTR (para [0020] - "SEQ ID NOs: 1,... and 168 are DNA sequences of regulatory expression element groups (EXPs) comprising a promoter sequence operably linked 5' to a leader sequence which is operably linked 5' to an intron sequence."; para [0037] - "Alternately, promoters may be synthetically produced or manipulated DNA molecules."; para [0039] - "Any of the promoters presented as SEQ ID NOs: 2, 6, ... and 169 and fragments or enhancers derived therefrom can be used to make chimeric regulatory element compositions"), wherein said DNA sequence is operably linked to a heterologous transcribable DNA molecule (Claim 1 - "A recombinant DNA molecule comprising a DNA sequence selected from ... wherein said DNA sequence is operably linked to a heterologous transcribable DNA molecule.").

Monsanto teaches (instant claim 9) a transgenic plant cell comprising a recombinant DNA molecule (Abstract - "The invention provides novel recombinant DNA molecules and constructs useful for modulating gene expression in plants, plant cells"; para [0085] - "The invention also includes and provides transformed plant cells comprising a DNA molecule of the invention. The transformed or transgenic plant cells of the invention include regenerable and/or non-regenerable plant cells.").

As said technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Groups I+ therefore lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-17 limited to SEQ ID NO: 1

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-17	YES
	Claims	NONE	NO
Inventive step (IS)	Claims	1-17	YES
	Claims	NONE	NO
Industrial applicability (IA)	Claims	1-17	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-17 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a recombinant DNA molecule comprising SEQ ID NO: 1.

Regarding claims 1 and 9, US 2016/0177326 A1 to Monsanto Technology, LLC. (hereinafter "Monsanto") teaches a transgenic plant cell comprising a recombinant DNA molecule (Abstract - "The invention provides novel recombinant DNA molecules and constructs useful for modulating gene expression in plants, plant cells"; para [0085] - "The invention also includes and provides transformed plant cells comprising a DNA molecule of the invention. The transformed or transgenic plant cells of the invention include regenerable and/or non-regenerable plant cells.") comprising a DNA sequence comprising synthetic promoter, leader, enhancer, intron or 3' UTR (para [0020] - "SEQ ID NOs: 1,... and 168 are DNA sequences of regulatory expression element groups (EXPs) comprising a promoter sequence operably linked 5' to a leader sequence which is operably linked 5' to an intron sequence."; para [0037] - "Alternately, promoters may be synthetically produced or manipulated DNA molecules."; para [0039] - "Any of the promoters presented as SEQ ID NOs: 2, 6, ... and 169 and fragments or enhancers derived therefrom can be used to make chimeric regulatory element compositions"), wherein said DNA sequence is operably linked to a heterologous transcribable DNA molecule (Claim 1 - "A recombinant DNA molecule comprising a DNA sequence selected from ... wherein said DNA sequence is operably linked to a heterologous transcribable DNA molecule.").

Monsanto does not specifically teach a recombinant DNA molecule comprising a DNA sequence consisting of: a sequence with at least 85 percent sequence identity to SEQ ID NO: 1 or a fragment of SEQ ID NO:1, wherein the fragment has gene-regulatory activity.

US 2011/0167514 A1 to Brover et al. (hereinafter "Brover") teaches nucleic acid sequence SEQ ID NO: 10904 that exhibits 8.5% match to claimed SEQ ID NO: 1 (SEQ ID NO: 10904 nts 65-396 has 8.5% identity to SEQ ID NO: 1 nts 89-393), yet does not teach a fragment of SEQ ID NO: 10904 comprising gene-regulatory activity.

There is no prior art on record that discloses the claimed subject matter, specifically, a nucleic acid molecule comprising at least 85% identity to claimed SEQ ID NO: 1 or a fragment of SEQ ID NO:1, wherein the fragment has gene-regulatory activity.

Regarding claims 2-8, the claims are dependent upon claim 1, claims 10-17 are dependent upon claim 9, and therefore also meet the criteria for substantially the same reasons.

Claims 1-17 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.